

IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION

EARL RINGO et al.,)
Plaintiffs,)
)
v.) 09-4095-CV-C-NKL
)
GEORGE A. LOMBARDI et al.,)
Respondent.)

REPLY TO PLAINTIFF'S SUPPLEMENTAL SUGGESTIONS

Plaintiffs have filed a supplemental pleading bringing the recent decision in *Pliva Inc. v. Mensing*, No. 09-993, 2011 WL 2472790 (U.S. June 23, 2011) to this Court's attention. Plaintiffs argue that *Pliva* supports their claim that Defendants violate federal law by having non-medical personnel push the plunger on syringes administering lethal chemicals, at the direction of and under the observation of, a board certified anesthesiologist, but without a written prescription from the anesthesiologist.

Pliva is a case about using the impossibility of complying with both state and federal law as a defense to a suit for failing to comply with state law about the contents of warning labels on generic drugs. Federal law places a duty on generic drug manufacturers to place warning labels on their products that are identical to the warning labels used on brand name versions of the same drug. Therefore it was impossible for a generic manufacturer to comply with a state law requiring a more extensive warning label and the federal law which created a duty of sameness. The Court found that the generic manufacturer should not be subject to

liability for not doing the impossible act of having a label that both complied with state law but was identical to a brand name label that did not comply with state law. The decision exists harmoniously with *Wyeth v. Levine*, 555 U.S. 555 (2009), a decision that holds that manufacturers of brand name drugs are liable for failure to comply with state law labeling requirements, even if the products have labels that have been approved by federal regulators.

Pliva does contain *dicta*, rejected by a majority of the Court, criticizing the existing method of pre-emption analysis. The current method of analysis contains a presumption that Congress does not intend to repeal state law on matters of health and safety. Part III-B-2 of the *Pliva* opinion contains language asserting that federal courts should not make particular efforts to reconcile apparent conflicts in federal and state law so that they can be read to exist harmoniously without conflict. But that position was not adopted by the majority of the Court. Justice Kennedy as well as the four dissenting Justices did not adopt the reasoning in Part III-B-2 that one should abandon the well established presumption that Congress does not intend to pre-empt state laws dealing with health and safety.

Pliva does not deal with Defendants' arguments about standing, Congressional intent that the FDCA and CSA only be enforced by the federal government, the necessary use of plain statement rule requirements in areas traditionally left to the states where federal intervention would involve the federal state balance, Eleventh Amendment immunity, and merits analysis that the FDCA and CSA are not intended to, and do not, apply to executions (See Document 213).

In order for *Pliva* to be potentially helpful to Plaintiffs in this case, Defendants' arguments on all those issues in this case would have to be wrong, and the numerous courts that have rejected claims similar or identical to Plaintiffs' claims in this case without reaching the level of textual analysis of the relevant statutes and regulations would also have to be wrong. But even if all that were true *Pliva* is still not really helpful to the plaintiffs in this case.

Pliva is narrow case about impossibility of compliance with federal and state law creating a defense to a suit for violating state law where compliance with state law was impossible under federal law. Even if one assumes that all Defendants' arguments in the summary judgment motion are wrong, and that all the courts that rejected similar or identical claims to those presented by Plaintiffs in this case are also wrong, analysis of the text of the relevant statutes and regulations still does not support Plaintiffs' argument that compliance with both federal law and state law is impossible in this case. 21 C.F.R. §1306.11(b) states that an individual practitioner may administer or dispense directly a controlled substance without a prescription. 21 U.S.C.A. §802(2)(a) defines administer as direct application of a controlled substance by a practitioner, or in his presence by his authorized agent. There is no real conflict between the applicable federal regulations and statutes and the Missouri execution protocol. Assuming for the sake of argument that the FDCA and CSA even apply in the context of executions, and assuming for the sake of argument that these statutes could be enforced by private individuals against the Several States, a plain reading of the relevant

statutes and regulations indicates no federal law is violated by the administration of the lethal chemical or chemicals during an execution, on the command of and under the observation of a licensed anesthesiologist. This would be true even if the *dicta* in the *Pliva* decision, suggesting abandonment of the well established presumption that Congress does not intend to repeal existing state law, had been adopted by a majority of the Court. But that *dicta* was not adopted by a majority of the Court and pre-emption analysis should continue to strive to read federal law as not creating impossibility of compliance with state law where this is at all possible.

But it is not necessary to reach that level of analysis, and summary judgment should be granted for Defendants for the reasons set out in Document 213, the summary judgment motion.

Respectfully submitted,

Chris Koster
Attorney General

/s/Michael J. Spillane

Michael Spillane
Assistant Attorney General
Missouri Bar No. 40704
P.O. Box 899
Jefferson City, MO 65102
Telephone: (573)751-7406
Facsimile: (573)751-2096

Certificate of Service

This pleading has been filed electronically on this 13th day of July, 2011 and should be served by this Court's electronic mailing system on counsel for all Plaintiffs.

/s/Michael J. Spillane

Michael J. Spillane